NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Cliniqa Corporation
495 Enterprise Street
San Marcos, CA 92078
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The design, development and manufacture of in-vitro diagnostic controls, calibrators, raw materials, reagents and kits for the diagnosis, management, detection of blood analytes, blood components, cardiac markers, cancer, therapeutic drug monitoring, and drugs of abuse.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.3440)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.3440
Certification Granted: Jul 22, 2009
Effective Date: Jul 10, 2018
Expiry Date: Jul 09, 2021

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

Annex to Certificate Number: MD19.3440

Scope of Registration:

The design, development and manufacture of in-vitro diagnostic controls, calibrators, raw materials, reagents and kits for the diagnosis, management, detection of blood analytes, blood components, cardiac markers, cancer, therapeutic drug monitoring, and drugs of abuse.

Activity	Location
Headquarters, Production	Cliniqa Corporation 495 Enterprise Street San Marcos, CA 92078 USA File No.: MD19.3440
Warehouse	Cliniqa Corporation 258 La Moree Road San Marcos, CA 92078 USA File No.: MD19.3440/A

Verified by:
Operations Manager